

Package leaflet: Information for the user

Centyl[®] K 2.5 mg/573 mg modified-release tablets bendroflumethiazide/potassium chloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Centyl[®] K modified-release tablets will be called Centyl K.

What is in this leaflet

1. What Centyl[®] K is and what it is used for
2. What you need to know before you take Centyl[®] K
3. How to take Centyl[®] K
4. Possible side effects
5. How to store Centyl[®] K
6. Contents of the pack and other information

1. What Centyl[®] K is and what it is used for

Centyl K contains two different types of active substances. One is called bendroflumethiazide, it is a diuretic (water tablet). The other active substance is called potassium chloride. It is a potassium supplement. The two medicines work at the same time in different ways.

Centyl K works by removing any excess water from your body. It will make you go to the toilet more. This means you will also lose potassium from your body. The potassium chloride in Centyl K is a supplement to replace some of the potassium you may lose.

Centyl K is used to treat:

- Oedema which occurs as a result of heart, kidney or liver problems. Oedema means that there is too much water in your body. Oedema can cause symptoms such as swollen ankles or trouble breathing.
- High blood pressure (hypertension). Your doctor may also decide to give you other blood pressure lowering medicines as well as this medicine.

2. What you need to know before you take Centyl[®] K

Do not take Centyl K

- If you are allergic (hypersensitive) to bendroflumethiazide or potassium chloride, or any of the other ingredients of this medicine (listed in section 6).
- If you know you have a condition called Addison's disease.
- If you have severe kidney problems or cannot pass water.
- If you have severe liver problems such as cirrhosis.
- If you have gout.
- If you have been told that you have abnormal levels of potassium, calcium, chloride, sodium or uric acid in your blood.
- If you know that you have a narrowing, blockage or ulcer in your digestive system, e.g. Crohn's Disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Centyl K

- If you have problems passing urine or any kidney problems.
- If you have high levels of calcium in your blood or any parathyroid hormone problems.
- If you have diabetes (as your dose of medicine may need to change).
- If you have low blood pressure.
- If you have ever had gout or problems with the amount of uric acid in your blood.
- If you have a condition called systemic lupus erythematosus (SLE).
- If you have heart problems.
- If you are taking another medicine called lithium for depression, as your dose of lithium may need to be lowered.
- If you have any condition which you are told could change the potassium levels in your body. Ask your doctor if you are unsure.
- If your adrenal glands are not working properly.
- If you are very dehydrated.
- If a large area of your skin has been damaged, e.g. badly burnt.
- If your bowel passes food or waste slowly.
- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Centyl K. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

When you are taking Centyl K, your doctor may take regular blood tests. This is very important in elderly patients, those with kidney or heart problems, or patients taking this medicine with other medicines.

Centyl K is banned for use in sport and will cause disqualification for sports people as it will be detected in urine during routine tests.

Other medicines and Centyl K

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes any medicines which you have bought without a prescription.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- A medicine called lithium for depression. Your doctor may lower your dose.
- Non-steroidal anti-inflammatory drugs, such as ibuprofen, for arthritis or aches or pains.
- Medicines for heart conditions (e.g. digoxin).
- Medicine for high blood pressure. Your doctor may need to change your dose.
- Medicines for abnormal heart rhythms, such as atrial fibrillation (i.e. antiarrhythmics).
- Tricyclic antidepressants. Your doctor may change your dose.
- Inhalers for asthma.
- Calcium supplements.
- Medicines for diabetes.
- Medicines which decrease sodium levels. Simultaneous use can increase the risk for low levels of sodium in the blood.
- Medicines for the management of cholesterol (e.g. cholestyramine).
- Medicines known to make you develop a skin rash in sunlight.
- Or if you are to be given a muscle relaxant (usually given by injection before a general anaesthetic). Please tell the hospital doctor that you are taking this medicine.

Pregnancy, breast-feeding and fertility

Please ask your doctor or pharmacist for advice before taking Centyl K:

- If you are pregnant, or think you might be pregnant or are planning to have a baby.
- Do not use Centyl K if you are pregnant, or think you might be pregnant, unless you have agreed it with your doctor first.
- If you are breast-feeding. Centyl K should not be taken by women who are breast-feeding.

Tell your doctor if you become pregnant while taking this medicine.

Driving and using machines

This medicine should not have any effect on your ability to use or drive machinery. You may feel dizzy after taking this medicine. If this happens, do not drive or use dangerous machinery for several hours.

Check with your doctor if you get any side effects that may affect your driving or using machinery.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. How to take Centyl® K

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Centyl K to take

The usual dose is 1 tablet daily. Your doctor may advise a different dose in some situations. You should take the tablet in the morning with a meal or after eating food. This will help to stop you getting up in the night to go to the toilet.

To remind you to take your medicine, it may help to take it when you do another regular activity such as having breakfast.

Remember to take this medicine with or after meals with at least a full glass of water or other liquid (milk or juice). The tablets must be swallowed whole. Do NOT crush or chew the tablets.

Adults:

- To treat oedema (excess water in the body): The dose will depend on your particular condition. Your doctor may give you between 1 and 4 tablets at the start of your treatment. Your dose will usually be reduced to 1 or 2 tablets daily, depending on your response. The tablets are usually taken as a single dose.
- To treat high blood pressure: The usual dose is 1 or 2 tablets daily as a single dose.

If you take more Centyl K than you should

Tell your doctor straight away. You may need to stop taking this medicine.

Signs that you have taken too much include passing more urine than usual, dry mouth, thirst, weakness, drowsiness, muscle pain, confusion, or if you take a fit, and irregular heartbeat.

If you forget to take Centyl K

If you forget to take your medicine, take it as soon as you remember. Then take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Centyl K

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In clinical trials, approximately 12 out of every 100 (12%) patients got a side effect.

Important side effects to look out for:

You must get urgent medical help straight away if you have any of the following symptoms.

Common (may affect up to 1 in 10 people)

- Low potassium levels in your blood, signs of this are muscle weakness, twitching or an abnormal heart rate.

Uncommon (may affect up to 1 in 100 people)

- Low magnesium levels in your blood, signs of this are weakness, muscle cramps, irregular heartbeat, tremors, confusion, disorientation, depression and high blood pressure.
- Problems with your heart such as an irregular heartbeat, increased heart rate or an increase in blood pressure or fluid retention.
- Low sodium levels in your body, signs of this are tiredness, confusion, muscle twitching, fits and coma.
- Too much or too little acid in your body. The signs of this may include changes to your breathing, chest pain, bluish skin colour, digestive upset, irritability, twitching, confusion, rapid or irregular heartbeat, headache and a drop in blood pressure.
- Low calcium levels in your blood, signs of this are pins and needles in your mouth, lips, feet or hands. It may also cause red or purple spots, muscle cramps and an irregular heartbeat.
- Kidney problems including kidney failure.

Other possible side effects which are less serious can occur:

Common (may affect up to 1 in 10 people)

- High uric acid levels in the blood which may cause painful swollen joints (gout).
- Dizziness (vertigo), especially when standing up due to low blood pressure or problems with your balance.
- Headache.
- Tiredness.
- Stomach upset.
- Feel sick (nausea).
- Digestive problems.
- Dry mouth and thirst.
- Feeling of weakness.
- Skin problems such as a rash, itchy blisters (eczema) or hives.
- Joint or muscle pain.
- You may experience flu-like symptoms such as a runny nose, fever, cough, tiredness or a feeling of weakness.

Uncommon (may affect up to 1 in 100 people)

- High levels of sugar in your blood (diabetes). The signs of high sugar levels are excessive thirst and hunger, needing to pass water (urine) more often, blurred vision, sleepiness, weight loss and a dry mouth.
- If you lose too much water from your body you may feel sick and tired.
- Low chloride levels in your blood; you usually will not notice this.
- You may gain weight.
- You may faint.
- You may experience difficulty in controlling your movements, e.g. unsteady walking.
- You may experience pins and needles or a tingling sensation in the hands or feet.
- You may experience changes in your sense of taste.
- Changes in your mood, e.g. depression.
- You may feel confused.
- Changes in your sleeping patterns.
- Your vision may become blurred.
- You may get red flushing of the face and neck.
- You may have a feeling of coldness in your hands or feet.
- You may have difficulty breathing, wheeziness and shortness of breath.

- You may experience pain in your stomach, vomiting, diarrhoea or constipation.
- High levels of parathyroid hormone which may cause a small increase in the level of calcium in your body. The likely signs of this are tiredness and weakness.
- Increased creatinine in your blood which may be a sign of kidney problems.
- You may sweat more.
- Itchy skin.
- You may have muscle cramps or twitching.
- You may pass more urine than normal.
- You may experience swelling of any part of the body including the face and legs.
- You may feel weak.
- Impotence.
- Skin rash in sunlight.

Frequency not known (cannot be estimated from the available data)

- High levels of calcium in your blood. Some of the symptoms of raised calcium levels may include fatigue, weakness, constipation, loss of appetite, nausea and vomiting.

Side effects that are known to happen with other diuretics but are not yet known to happen with Centyl K

- Low blood platelet count; you may bleed or bruise more easily than normal.
- Lack of white blood cells; you may get infections more often such as a sore throat or mouth ulcers.
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Centyl® K

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C. Keep the bottle tightly closed as the product is sensitive to moisture.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last date of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Centyl K contains

- The active substances are bendroflumethiazide (2.5 milligrams) and potassium chloride (573 milligrams) in each tablet.
- The other ingredients are: Tablet core: ethyl cellulose, glycerol, stearyl alcohol, magnesium stearate. Tablet coating: glycerol, hypromellose 3 cps, hypromellose 15 cps, citric acid monohydrate, saccharin sodium, talc, titanium dioxide (E171), polysorbate 20, patent blue V lake (E131), quinoline yellow lake (E104).

What Centyl K looks like and contents of the pack

Centyl K is a green, film-coated oval tablet.

Centyl K comes in packs of 100 and 250 modified-released tablets in a plastic bottle with a tamper evident closure and an integrated desiccant capsule, or as packed by your pharmacist.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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